General

Guideline Title

VA/DoD clinical practice guideline for the management of type 2 diabetes mellitus in primary care.

Bibliographic Source(s)

Management of Type 2 Diabetes Mellitus in Primary Care Work Group. VA/DoD clinical practice guideline for the management of type 2 diabetes mellitus in primary care. Version 5.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Apr. 160 p. [178 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Department of Veteran Affairs, Department of Defense. VA/DoD clinical practice guideline for the management of diabetes mellitus. Washington (DC): Department of Veteran Affairs, Department of Defense; 2010 Aug. 146 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 12, 2016 – Pioglitazone-containing Medicines: As a result of an updated review, the U.S. Food and Drug Administration (FDA) has concluded that use of the type 2 diabetes medicine pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) may be linked to an increased risk of bladder cancer. The labels of pioglitazone-containing medicines already contain warnings about this risk, and FDA has approved label updates to describe the additional studies reviewed.

Recommendations

Major Recommendations

Note from the Department of Veterans Affairs and the Department of Defense (VA/DoD) and the National Guideline Clearinghouse (NGC): The recommendations for the management of type 2 diabetes mellitus in the primary care setting are organized into 5 sections with 2

algorithms. The sections with accompanying recommendations are provided below. See the original guideline document for the algorithms and evidence tables with recommendations, including strength of recommendation, recommendation category, and supporting evidence citations.

The strength of recommendation grading (Strong For, Weak For, Strong Against, Weak Against) and recommendation categories (Reviewed, Not reviewed, New-added, New-replaced, Not changed, Amended, Deleted) are defined at the end of the "Major Recommendations" field.

General Approach to Type 2 Diabetes Mellitus Care

1. The Work Group recommends shared decision-making to enhance patient knowledge and satisfaction. (Strong for; Reviewed, New-added)
2. The Work Group recommends that all patients with diabetes should be offered ongoing individualized diabetes self-management education via various modalities tailored to their preferences, learning needs and abilities based on available resources. (Strong for; Reviewed, New-replaced)
3. The Work Group suggests offering one or more types of bidirectional telehealth interventions (typically health communication via computer, telephone or other electronic means) involving licensed independent practitioners to patients selected by their primary care provider as an adjunct to usual patient care. (Weak for; Reviewed, New-replaced)

Glycemic Control Targets and Monitoring

4. The Work Group recommends setting a glycosylated hemoglobin (HbA1c) target range based on absolute risk reduction of significant microvascular complications, life expectancy, patient preferences and social determinants of health. (Strong for; Reviewed, New-added)
5. The Work Group recommends developing an individualized glycemic management plan, based on the provider's appraisal of the risk-benefit ratio and patient preferences. (Strong for; Reviewed, Amended)
6. The Work Group recommends assessing patient characteristics such as race, ethnicity, chronic kidney disease, and non-glycemic factors (e.g., laboratory methodology and assay variability) when interpreting HbA1c, fructosamine and other glycemic biomarker results. (Strong for; Reviewed, New-added)
7. The Work Group recommends an individualized target range for HbA1c taking into account individual preferences, presence or absence of microvascular complications, and presence or severity of comorbid conditions (see Table 2 in the original guideline document). (Strong for; Reviewed, New-replaced)
8. The Work Group suggests a target HbA1c range of 6.0% to 7.0% for patients with a life expectancy greater than 10 to 15 years and absent or mild microvascular complications, if it can be safely achieved (see Table 2 in the original guideline document). (Weak for; Reviewed, New-replaced)
9. The Work Group recommends that in patients with type 2 diabetes, a range of HbA1c 7.0% to 8.5% is appropriate for most individuals with established microvascular or macrovascular disease, comorbid conditions, or 5 to 10 years life expectancy, if it can be safely achieved (See Table 2 in the original guideline document). (Strong for; Reviewed, New-added)
10. The Work Group suggests a target HbA1c range of 8.0% to 9.0% for patients with type 2 diabetes with life expectancy <5 years, significant comorbid conditions, advanced complications of diabetes, or difficulties in self-management attributable to, e.g., mental status, disability or other factors such as food insecurity and insufficient social support (see Table 2 in the original guideline document). (Weak for; Reviewed, New-replaced)
11. The Work Group suggests that providers be aware that HbA1c variability is a risk factor for microvascular and macrovascular outcomes. (Weak for; Reviewed, New-added)

Non-pharmacological Treatments

12. The Work Group recommends offering therapeutic lifestyle changes counseling that includes nutrition, physical activity, cessation of smoking and excessive use of alcohol, and weight control to patients with diabetes (see the NGC summaries of the VA/DoD Clinical Practice Guidelines [CPGs] for management of overweight and obesity and management of substance use disorders, and the VA/DoD CPG for tobacco use cessation). (Strong for; Not Reviewed, Amended)
13. The Work Group recommends a Mediterranean diet if aligned to patient's values and preferences. (Strong for; Reviewed, New-added)
14. The Work group recommends a nutrition intervention strategy reducing percent of energy from carbohydrate to 14% to 45% per day and/or foods with lower glycemic index in patients with type 2 diabetes who do not choose the Mediterranean diet. (Strong for; Reviewed, New-added)

Inpatient Care

15. The Work Group recommends against targeting blood glucose levels <110 mg/dL for all hospitalized patients with type 2 diabetes receiving insulin. (Strong against; Reviewed, Amended)

16. The Work Group recommends insulin be adjusted to maintain a blood glucose level between 110 and 180 mg/dL for patients with type 2 diabetes in critically ill patients or those with acute myocardial infarction. (Strong for; Reviewed, Amended)
17. The Work group recommends against the use of split mixed insulin regimen for all hospitalized patients with type 2 diabetes. (Strong against; Reviewed, New-added)
18. The Work Group suggests a regimen including basal insulin and short-acting meal time or basal insulin and correction insulin for non-critically ill hospitalized patients with type 2 diabetes. (Weak for; Reviewed, New-added)
19. The Work Group suggests providing medication education and diabetes survival skills to patients before hospital discharge. (Weak for; Reviewed, Amended)

Selected Complications and Conditions

20. The Work Group recommends performing a comprehensive foot risk assessment annually. (Strong for; Not Reviewed, Amended)
21. The Work Group recommends referring patients with limb-threatening conditions to the appropriate level of care for evaluation and treatment. (Strong for; Not Reviewed, Amended)
22. The Work Group recommends a retinal examination (e.g., dilated fundus examination by an eye care professional or retinal imaging with interpretation by a qualified, experienced reader) be used to detect retinopathy. (Strong for; Not Reviewed, Amended)
23. The Work Group suggests screening for retinopathy at least every other year (biennial screening) for patients who have had no retinopathy on all previous examinations. More frequent retinal examinations in such patients should be considered when risk factors associated with an increased rate of progression of retinopathy are present. Patients with existing retinopathy should be managed in conjunction with an eye care professional and examined at intervals deemed appropriate for the level of retinopathy. (Weak for; Not Reviewed, Amended)
24. The Work group recommends that all females with pre-existing diabetes or personal history of diabetes and who are of reproductive potential be provided contraceptive options education and education on the benefit of optimizing their glycemic control prior to attempting to conceive. (Strong for; Not Reviewed, Amended)
25. The Work Group recommends that all females with pre-existing diabetes or personal history of diabetes who are planning pregnancy be educated about the safest options of diabetes management during the pregnancy and referred to a maternal fetal medicine provider (when available) before, or as early as possible, once pregnancy is confirmed. (Strong for; Not Reviewed, Amended)

Refer to the original guideline document for considerations for pharmacological therapy.

Definitions

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Using these elements, the grade of each recommendation is presented as part of a continuum:

- Strong For (or "The Work Group recommends offering this option …")
- Weak For (or "The Work Group suggests offering this option …")
- Weak Against (or "The Work Group suggests not offering this option …")
- Strong Against (or "The Work Group recommends against offering this option …")

Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

Recommendation Categories and Definitions

For use in the 2017 diabetes mellitus CPG, a set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated.

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) and Garcia et al. (2014).

Abbreviation: CPG: clinical practice guideline

Clinical Algorithm(s)

Algorithms are provided in the original guideline document for:

- Module A: General Care and Treatment
- Module B: Diabetes Self-Management Education

Scope

Disease/Condition(s)

- Type 2 diabetes mellitus
- Pre-diabetes
- Complications of diabetes mellitus, including hypertension, dyslipidemia, retinopathy, microvascular and macrovascular complications

Guideline Category

Counseling

Management

Prevention

Risk Assessment

Screening

Treatment

Clinical Specialty

Cardiology

Endocrinology

Family Practice

Internal Medicine

Nephrology

Nutrition

Ophthalmology

Optometry

Podiatry

Preventive Medicine

Intended Users

Advanced Practice Nurses

Dietitians

Health Care Providers

Hospitals

Nurses

Optometrists

Pharmacists

Physician Assistants

Physicians

Podiatrists

Guideline Objective(s)

- To assist providers in managing or co-managing patients with type 2 diabetes mellitus
- To assist healthcare providers in all aspects of patient care, including diagnosis, treatment, and follow-up
- To improve the patient's health and well-being by guiding health providers, especially in primary care, to the management pathways that are supported by evidence

Target Population

Adult patients (18 years or older) with type 2 diabetes mellitus (T2DM) who are eligible for care in the Department of Veterans Affairs and Department of Defense (VA and DoD) healthcare delivery systems, which includes Veterans, deployed and non-deployed Active Duty Service Members, and their adult family

Refer to the original guideline document for specific populations for key questions.

Note: This clinical practice guideline (CPG) does not provide recommendations for the management of DM in children, adolescents, or pregnant/nursing women.

Interventions and Practices Considered

1. General approach to type 2 diabetes mellitus care
    - Shared decision-making
    - Individualized diabetes self-management education
    - Bidirectional telehealth interventions (e.g., health communication via computer, telephone or other electronic means)
2. Glycemic control targets and monitoring
    - Setting glycosylated hemoglobin (HbA1c) target range
    - Developing an individualized glycemic management plan
    - Assessing patient characteristics when interpreting HbA1c, fructosamine and other glycemic biomarker results
3. Non-pharmacological treatments
    - Therapeutic lifestyle changes (nutrition, physical activity, cessation of smoking and excessive use of alcohol, and weight control)
    - Mediterranean diet
    - Dietary carbohydrate reduction
4. Inpatient care
    - Targeting blood glucose levels <110 mg/dL (*recommendation against*)
    - Maintaining a blood glucose level between 110 and 180 mg/dL in critically ill patients or those with acute myocardial infarction
    - Use of split mixed insulin regimen (*recommendation against*)
    - Regimen including basal insulin and short-acting meal time or basal insulin and correction insulin for non-critically ill hospitalized patients
    - Providing medication education and diabetes survival skills to patients before hospital discharge
5. Management of selected complications and conditions
    - Annual comprehensive foot risk assessment
    - Referral of patients with limb-threatening conditions
    - Retinal examinations/screening for retinopathy
    - Contraceptive options education and education on optimizing glycemic control in females of reproductive age

Major Outcomes Considered

- Glucose variability
- Blood pressure
- Hypoglycemia/hyperglycemia
- Dehydration
- Infection
- Glycosylated hemoglobin (HbA1c) levels
- Cardiovascular outcomes (congestive heart failure, coronary artery disease, stroke, myocardial infarction)
- Dyslipidemia
- Diabetes-related microvascular outcomes (nephropathy, retinopathy, neuropathy)
- Weight change
- Patient psychosocial coping
- Adherence to medication management/regimen
- Length of hospital stay
- 30-day readmission
- Quality of life
- Mortality

Table A-4 in the original guideline document lists the outcomes of interest by the key question.

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Developing the Scope and Key Questions

The Champions, along with the Work Group, were tasked with identifying key questions (KQs) to guide the systematic review of the literature on diabetes mellitus (DM). These questions, which were developed in consultation with the Lewin team, addressed clinical topics of the highest priority for the Department of Veterans Affairs and Department of Defense (VA and DoD) populations. The KQs follow the population, intervention, comparison, outcome, timing and setting (PICOTS) framework for evidence questions, as established by the Agency for Healthcare Research and Quality (AHRQ). Table Aâ€1 in the original guideline document provides a brief overview of the PICOTS typology.

The Champions, Work Group, and evidence review team carried out several iterations of this process, each time narrowing the scope of the CPG and the literature review by prioritizing the topics of interest. Due to resource constraints, all developed KQs could not be included in the systematic evidence review. Thus, the Champions and Work Group determined which questions were of highest priority and those were included in the review. Table A-5 in the original guideline document contains the final set of KQs used to guide the systematic evidence review for this CPG.

Conducting the Systematic Review

Extensive literature searches using the search terms and strategy included in Appendix H of the original guideline document identified 5,012 citations potentially addressing the KQs of interest to this evidence review. Of those, 1,940 were excluded upon title review for clearly not meeting inclusion criteria (e.g., not pertinent to the topic, not published in English, published prior to study inclusion publication date, not a full-length article). Overall, 3,072 abstracts were reviewed with 2,328 of those being excluded for the following reasons: not a systematic review (SR) or clinical study, did not address a KQ of interest to this review, did not enroll a population of interest, or published prior to January 1, 2009. A total of 744 full-length articles were reviewed. Of those, 453 were excluded at a first-pass review for the following: not addressing a key question of interest, not enrolling the population of interest, not meeting inclusion criteria for clinical study or SR, not meeting inclusion criteria for any key question, or being a duplicate. A total of 291 full-length articles were thought to address one or more key questions and were further reviewed. Of these, 233 were ultimately excluded. Reasons for their exclusion are presented in Figure A-1 of the original guideline document.

Overall, 58 studies addressed one or more of the KQs and were considered as evidence in this review. Table A-5 in the original guideline document indicates the number of studies that addressed each of the questions.

Criteria for Study Inclusion/Exclusion

General Criteria

- Clinical studies or SRs published on or after January 1, 2009 to March 25, 2016, except for KQ7 (see Key Question Specific Criteria below). If multiple SRs address a key question, the Work group selected the most recent and/or comprehensive review. SRs were supplemented with clinical studies published subsequent to the SR.
- Studies must be published in English.
- Publication must be a full clinical study or SR; abstracts alone were not included. Similarly, letters, editorials, and other publications that are not full-length clinical studies were not accepted as evidence.
- Intervention studies had a treatment or management style and were a prospective, randomized controlled trial with an independent control group, unless otherwise noted (see Key Question Specific Criteria below). The ideal diagnostic study compares clinical outcomes after diagnostic technology evaluation versus clinical evaluation, or compares clinical outcomes linked to different diagnostic technologies. Non-comparative diagnostic studies reporting only characteristics of the diagnostic test (e.g., sensitivity, specificity, repeatability) were excluded. However, non-comparative diagnostic studies that report a change in management strategy or patient outcomes (e.g., evidence of organic based disease patterns) were considered.
- Study must have enrolled at least 20 patients (10 per study group) unless otherwise noted. (see Key Question Specific Criteria below.)
- Study must have reported on an outcome of interest. Study must have enrolled a patient population in which at least 80% of patients had a diagnosis of type 2 diabetes mellitus (T2DM). If the percentage is less than 80%, then data must have been reported separately for this patient subgroup.

Key Question Specific Criteria

- For KQ 1, acceptable study designs included SRs, randomized controlled trials (RCTs), including follow-up studies of RCTs, cohorts and

pre-planned, prospective analyses of those studies. Retrospective analyses were not included.

- For KQs 2-4, 8, and 9, acceptable study designs included SRs of RCTs and/or individual RCTs.
- For KQ 5, acceptable study designs included SRs of acceptable study designs, individual RCTs or prospective nonrandomized controlled studies.
- For KQ 6, acceptable study designs included SRs of acceptable study designs, RCTs or prospective cohort studies that statistically compared outcomes for patients with T2DM and higher versus lower glucose variability. Large retrospective studies (200 patients minimum) that performed multivariate statistical analyses of the effect of higher and lower glucose variability on patient outcomes were also acceptable.
- For KQ7, it was determined after initial searches that the KQ required additional refinement and updated searches. Searches were updated to capture clinical studies or SRs published on or after January 1, 2009 to June 14, 2016.
- For KQ7, acceptable study designs included SRs, prospective blinded trials, cohort, or case-control studies comparing diabetes management metrics to glycosylated hemoglobin (HbA1c). For assessment of diagnostic accuracy, diagnostic cohort studies that compare a diagnostic test(s) to a reference standard (HbA1c) within the same patient were acceptable.
- For KQ9, trials set outside of the U.S. were considered to be out of scope, as the potential differences in education, support, cultural norms, and socioeconomic setting could potentially limit applicability. Additionally, the minimum sample size per treatment arm was 50 patients.

Literature Search Strategy

Bibliographic Database Information

The following databases were searched for relevant information:

- The Cochrane Central Register of Controlled Trials (CENTRAL): 1/1/2009-4/11/16 (Wiley)
- The Cochrane Database of Methodology Reviews (Methodology Reviews: 1/1/2009-4/11/16 (Wiley)
- The Cochrane Database of Systematic Reviews (Cochrane Reviews): 1/1/2009-4/11/16 (Wiley)
- Database of Abstracts of Reviews of Effects: 1/1/2009-4/11/16 (Wiley)
- EMBASE (Excerpta Medica): 1/1/2009-4/4/16; KQ7: 1/1/2009-6/14/16 (Elsevier)
- Health Technology Assessment Database (HTA): 1/1/2009-4/11/16 (Wiley)
- MEDLINE/PreMEDLINE: 1/1/2009-4/4/16; KQ7: 1/1/2009-6/14/16 (OVIDSP)
- PubMed (In-process and Publisher records): 1/1/2009-4/4/16; KQ7: 1/1/2009-6/14/16 (NLM)

Gray Literature Resources

- AHRQ: 1/1/2009-4/11/16 (AHRQ)
- Healthcare Standards database: 1/1/2009-4/11/16 (ECRI Institute)
- National Guideline Clearinghouse™: 1/1/2009-4/11/16 (AHRQ)
- National Institute of Health and Care Excellence: 1/1/2009-4/11/16 (United Kingdom National Health Service [NHS])

Number of Source Documents

Overall, 58 studies addressed one or more of the key questions and were considered as evidence in the review. See Figure A-1 in the original guideline document for a study flow diagram.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence and Definitions*

High quality — Further research is very unlikely to change confidence in the estimate of effect.
Moderate quality — Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.

Low quality — Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very low quality — Any estimate of effect is very uncertain.

*Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., Schünemann, H. J. & the GRADE Working Group. (2008). GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ, 336*, 924-926.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Abstracting and Managing Data

For each study included in the review, the following study level details were abstracted: country, purpose, and quality rating. For previous systematic reviews, the search strategy used, study selection criteria, and overall information about the evidence base were reported, including number of included studies and overall patients enrolled. For all studies, the reviewers abstracted data about characteristics of the included patients and interventions being assessed.

Assessing Individual Studies' Methodological Quality (i.e., Internal Validity or Risk of Bias)

As per the Department of Veterans Affairs/Department of Defense (VA/DoD) *Guidelines for Guidelines* document, risk-of-bias (or study quality) of individual studies and previous systematic reviews was assessed using the U.S. Preventive Services Task Force (USPSTF) method. Each study was assigned a rating of Good, Fair, or Poor based on sets of criteria that vary depending on study design. Detailed lists of criteria and definitions of Good, Fair, or Poor ratings for different study designs appear in Appendix VII of the USPSTF procedure manual .

Data Synthesis

The evidence review team used a narrative approach to synthesizing the evidence for all the Key Questions. As indicated in the VA/DoD *Guidelines for Guidelines* document, the first line of evidence was previous systematic reviews. For questions in which a previous review was available, individual studies that met this review's inclusion criteria were used to supplement or update the previous review. The reviewers considered whether subsequent evidence supports the conclusions reported in the previous review. For questions for which no previous review was available, the reviewers summarized the overall findings for the outcomes of interest of the studies that addressed a key question.

Assessing the Overall Quality of the Body of Evidence for an Outcome

The overall quality of the body of evidence supporting the findings for the outcomes of interest in this report was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. The GRADE system primarily involves consideration of the following factors: overall study quality (or overall risk of bias or study limitations), consistency of evidence, directness of evidence, and precision of evidence. Given time and resources, other factors such as publication bias may also be considered. For more information on the GRADE system go to the GRADE working group Web site .

The GRADE system rates the overall quality of the evidence as High, Moderate, Low, and Very Low (see the "Rating Scheme for the Strength of the Evidence" field). For instance, a body of evidence that consists of randomized controlled trials (RCTs) automatically starts with a rating of high quality. This rating can be downgraded if some of the RCTs have serious flaws such as lack of blinding of outcome assessors, not reporting concealment of allocation, or high dropout rate. Similarly, the quality can be downgraded or further downgraded if inconsistencies of findings are present or if there is a lack of precision surrounding an outcome's effect size.

Assessing Applicability

When describing the evidence base addressing a Key Question, the reviewers discussed aspects of the included studies, such as characteristics of included patients and treatments being assessed that may make the overall findings of the studies more or less applicable to the population, treatments, or outcomes of interest to this review.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The current document is an update to the 2010 Diabetes Mellitus Clinical Practice Guideline (DM CPG). The methodology used in developing the 2017 CPG follows the *Guideline for Guidelines*, an internal document of the Department of Veterans Affairs and Department of Defense (VA and DoD) Evidence-Based Practice Working Group (EBPWG) (see the "Availability of Companion Documents" field). This document provides information regarding the process of developing guidelines, including the identification and assembly of the Guideline Champions (Champions), and other subject matter experts from within the VA and DoD, known as the Work Group, and ultimately, the development and submission of a new or updated DM CPG.

The Champions and Work Group for this CPG were charged with developing evidence-based clinical practice recommendations and writing and publishing a guideline document to be used by providers within the VA/DoD healthcare systems. Specifically, the Champions and Work Group members for this guideline were responsible for identifying the key questions (KQs) of the most clinical relevance, importance, and interest for the management of patients with DM. The Champions and the Work Group also provided direction on inclusion and exclusion criteria for the evidence review and assessed the level and quality of the evidence. The amount of new scientific evidence that had accumulated since the previous version of the CPG was also taken into consideration in the identification of the KQs. In addition, the Champions assisted in:

- Identifying appropriate disciplines of individuals to be included as part of the Work Group
- Directing and coordinating the Work Group
- Participating throughout the guideline development and review processes

The VA Office of Quality, Safety and Value, in collaboration with the Office of Evidence Based Practice, U.S. Army Medical Command, the proponent for CPGs for the DoD, identified two clinical leaders as Champions for the 2017 DM CPG.

The Lewin Team, including the Lewin Group, Duty First Consulting, ECRI Institute, and Sigma Health Consulting, LLC, was contracted by the VA and DoD to support the development of this CPG and conduct the evidence review. The first conference call was held in December 2015, with participation from the contracting officer's representative, leaders from the VA Office of Quality, Safety and Value and the DoD Office of Evidence Based Practice, and the Champions. During this call, participants discussed the scope of the guideline initiative, the roles and responsibilities of the Champions, the project timeline, and the approach for developing and prioritizing specific research questions on which to base a systematic review (SR) about the management of DM. The group also identified a list of clinical specialties and areas of expertise that are important and relevant to the management of DM, from which Work Group members were recruited. The specialties and clinical areas of interest included endocrinology, internal medicine, nutrition, pharmacy, health education, nursing, medical management, ambulatory care, and family practice.

The guideline development process for the 2017 CPG update consisted of the following steps:

1. Formulating and prioritizing KQs
2. Conducting a patient focus group
3. Conducting the SR
4. Convening a face-to-face meeting with the Champions and Work Group members
5. Drafting and submitting a final CPG about the management of DM to the VA/DoD EBPWG

Appendix A in the original guideline document provides a detailed description of each of these tasks.

Convening the Face-to-face Meeting

In consultation with the contracting officer's representative, the Champions, and the Work Group, the Lewin Team convened a three and a half day face-to-face meeting of the Champions and Work Group members on June 21-24, 2016. These experts were gathered to develop and draft the clinical recommendations for an update to the 2010 DM CPG. Lewin presented findings from the evidence review of KQs 1-9 in order to facilitate and inform the process.

Under the direction of the Champions, the Work Group members were charged with interpreting the results of the evidence review, and asked to categorize and carry forward recommendations from the 2010 DM CPG, modifying the recommendations as necessary. The members also developed new clinical practice recommendations not presented in the 2010 DM CPG, based on the 2016 evidence review. The subject matter

experts were divided into three smaller subgroups at this meeting.

As the Work Group members drafted clinical practice recommendations, they also assigned a grade for each recommendation based on a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) and U. S. Preventive Services Task Force (USPSTF) methodology. Each recommendation was graded by assessing the quality of the overall evidence base, the associated benefits and harms, the variation in values and preferences, and other implications of the recommendation.

In addition to developing recommendations during the face-to-face meeting, the Work Group members also revised the 2010 DM CPG algorithms to reflect the new and amended recommendations. They discussed the available evidence as well as changes in clinical practice since 2010, as necessary, to update the algorithms.

Grading Recommendations

This CPG uses the GRADE methodology to assess the quality of the evidence base and assign a grade for the strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation:

- Balance of desirable and undesirable outcomes
- Confidence in the quality of the evidence
- Values and preferences
- Other implications, as appropriate:
    - Resource use
    - Equity
    - Acceptability
    - Feasibility
    - Subgroup considerations

The framework in Table A-7 in the original guideline document ("Evidence to Recommendations Framework") was used by the Work Group to guide discussions on each domain.

The strength of a recommendation is defined as the extent to which one can be confident that the desirable effects of an intervention outweigh its undesirable effects and is based on the framework, which combines the four domains. GRADE methodology does not allow for recommendations to be made based on expert opinion alone. While strong recommendations are usually based on high or moderate confidence in the estimates of effect (quality of the evidence) there may be instances where strong recommendations are warranted even when the quality of evidence is low. In these types of instances where the balance of desirable and undesirable outcomes and values and preferences played large roles in determining the strength of a recommendation, this is explained in the discussion section for the recommendation.

The GRADE of a recommendation is based on the following elements:

- Four decision domains used to determine the strength and direction
- Relative strength (Strong or Weak)
- Direction (For or Against)

Reconciling 2010 Clinical Practice Guideline Recommendations

Evidence-based CPGs should be current, which typically requires revisions of previous guidelines based on new evidence, or as scheduled, subject to time-based expirations. For example, the USPSTF has a process for refining or otherwise updating its recommendations pertaining to preventive services. Further, the inclusion criteria for the National Guideline Clearinghouse specify that a guideline must have been developed, reviewed, or revised within the past five years.

The DM Guideline Work Group focused largely on developing new and updated recommendations based on the evidence review conducted for the priority areas addressed by the KQs. In addition to those new and updated recommendations, the Guideline Work Group considered, without complete review of the relevant evidence, the current applicability of other recommendations that were included in the previous 2010 DM CPG, subject to evolving practice in today's environment.

A set of recommendation categories was adapted from those used by the National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which previous recommendations could have been updated. In brief, the categories took into account whether or not the evidence that related to a recommendation was systematically reviewed, the degree to which the recommendation was modified, and the degree to which a recommendation is relevant in the current patient care environment and within the scope of the CPG. Additional information regarding these categories and their definitions can be found in Appendix A

in the original guideline document. The categories for the recommendations included in the 2017 version of the guideline are noted in the Recommendations (see the "Major Recommendations" field). The categories for the recommendations from the 2010 DM CPG are noted in Appendix F in the original guideline document.

The CPG Work Group recognized the need to accommodate the transition in evidence-rating systems from the 2010 DM CPG to the current CPG. In order to report the strength of all recommendations using a consistent format (i.e., the GRADE system), the CPG Work Group converted the USPSTF strengths of the recommendation accompanying the carryover recommendations from the 2010 guideline to the GRADE system. As such, the CPG Work Group considered the strength of the evidence cited for each recommendation in the 2010 DM CPG as well as harms and benefits, values and preferences, and other implications, where possible. The CPG Work Group referred to the available evidence as summarized in the body of the 2010 DM CPG and did not re-assess the evidence systematically. In some instances, peer-reviewed literature published since the 2010 DM CPG was considered along with the evidence base used for that CPG. Where such newer literature was considered when converting the strength of the recommendation from the USPSTF to the GRADE system, it is referenced in the discussion that follows the corresponding recommendation, as well as in Appendix E of the original guideline document.

The CPG Work Group recognizes that, while there are practical reasons for incorporating findings from a previous SR, previous recommendations, or recent peer-reviewed publications into an updated CPG, doing so does not involve an original, comprehensive SR and, therefore, may introduce bias.

Summary of Patient Focus Group Methods and Findings

When forming guideline recommendations, consideration should be given to the values of those most affected by the recommendations. Patients bring perspectives, values, and preferences into their healthcare experience, and more specifically their DM care experience, that vary from those of clinicians. These differences and the variability between patients' perspectives can affect decision making in various situations, and should thus be highlighted and made explicit due to their potential to influence a recommendation's implementation. Focus groups can be used as an efficient method to explore ideas and perspectives of a group of individuals with an a priori set of assumptions or hypotheses and collect qualitative data on a thoughtfully predetermined set of questions.

Therefore, as part of the effort to update this CPG, VA and DoD Leadership, along with the DM CPG Work Group and Lewin, held a patient focus group on March 8, 2016, at the VA Puget Sound Health Care System - American Lake Division in Tacoma, Washington. The aim of the focus group was to further the understanding of the perspective of patients receiving treatment for DM within the VA and/or DoD healthcare systems. The focus group explored patient perspectives on a set of topics related to management of DM in the VA and DoD healthcare systems, including patients' knowledge of DM treatment options, views on the delivery of care, patients' perspective on their needs and preferences, and the impact of DM on their lives.

It is important to note the focus group was a convenience sample and the Working Group recognizes the limitations inherent in the small sample size. Less than 10 people were included in the focus group consistent with the requirements of the federal Paperwork Reduction Act, 1980. The Work Group acknowledges that the sample of patients included in this focus group may not be representative of all VA and DoD patients receiving treatment for DM. Patient perspective and input provided, while invaluable, is not generalizable given the broad characteristics of various key demographic groups of persons with DM. Further, time limitations for the focus group prevented exhaustive exploration of all topics related to DM treatment in the VA and DoD and the patients' broader experiences with their care. Thus, the Working Group made decisions regarding the priority of topics to discuss at the focus group. These limitations, as well as others, were considered throughout the use of the information collected from the discussion for guideline development.

Recruitment for participation in the focus group was managed by the Champions and VA and DoD Leadership, with assistance from coordinators at the facility at which the focus group took place.

The following concepts are aspects of care that are important to patients that emerged from the discussion. These concepts were needed and important parts of the participants' care and added to the Work Group's understanding of patient values and perspectives. Additional details regarding the patient focus group methods and findings can be found in Appendix D of the original guideline document.

Drafting and Submitting the Final Clinical Practice Guideline

Following the face-to-face meeting, the Champions and Work Group members were given writing assignments to craft discussion sections to support each of the new recommendations and/or to update discussion sections from the 2010 DM CPG to support the amended "carried forward" recommendations. The Work Group also considered tables, appendices, and other sections from the 2010 DM CPG for inclusion in the update. During this time, the Champions and Work Group also made additional revisions to the algorithms, as necessary.

Rating Scheme for the Strength of the Recommendations

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Using these elements, the grade of each recommendation is presented as part of a continuum:

- Strong For (or "The Work Group recommends offering this option …")
- Weak For (or "The Work Group suggests offering this option …")
- Weak Against (or "The Work Group suggests not offering this option …")
- Strong Against (or "The Work Group recommends against offering this option …")

Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

Recommendation Categories and Definitions

For use in the 2017 Diabetes Mellitus (DM) Clinical Practice Guideline (CPG), a set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated.

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) and Garcia et al. (2014).

Abbreviation: CPG: clinical practice guideline

See Appendix A in the original guideline document for further details on categorization.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

After developing the initial draft of the updated Clinical Practice Guideline (CPG), an iterative review process was used to solicit feedback on and make revisions to the CPG. Once they were developed, the first two drafts of the CPG were posted on a wiki Web site for a period of 14 to 20 business days for internal review and comment by the Work Group. All feedback submitted during each review period was reviewed and discussed by the Work Group and appropriate revisions were made to the CPG.

Draft 3 of the CPG was made available for peer review and comment. This process is described in "Peer Review Process" section in the original guideline document. After revisions were made based on the feedback received during the peer review and comment period, the Champions presented the CPG to the Evidence Based Practice Work Group (EBPWG) for their approval. Changes were made based on feedback from the EBPWG and the guideline was finalized.

The final 2017 diabetes mellitus (DM) CPG was submitted to the EBPWG in April 2017.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Table A-5 in the original guideline document indicates the number and type of studies that addressed each of the questions. The evidence base consists primarily of randomized controlled trials and observational studies.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Successful implementation of this guideline will facilitate shared decision-making to establish patient goals, assessment of the patient's situation and determination of the treatment methods to achieve the goals, and reduction in the risk of preventable complications while improving quality of life.

See the "Discussion" sections in the original guideline document for information on the balance between benefits and harms for specific recommendations.

Potential Harms

Side effects of pharmacological therapy can include drug-drug interactions, hypoglycemia, and specific adverse drug effects.

Refer to the original guideline document, including Appendix B, for details regarding specific antidiabetic medications.

Contraindications

Contraindications

Many routine medications used in type 2 diabetes mellitus are contraindicated during pregnancy. Refer to Appendix B in the original guideline document for additional information on contraindications to antidiabetic drugs.

Qualifying Statements

Qualifying Statements

- The Department of Veterans Affairs (VA) and The Department of Defense (DoD) guidelines are based on the best information available at the time of publication. They are designed to provide information and assist in decision-making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.
- This Clinical Practice Guideline is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendations.
- Variations in practice will inevitably and appropriately occur when providers take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in any particular clinical situation.
- These guidelines are not intended to represent Department of Veterans Affairs or TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting your regional TRICARE Managed Care Support Contractor.

Implementation of the Guideline

Description of Implementation Strategy

The Clinical Practice Guideline (CPG) and algorithms are designed to be adaptable with consideration of local needs and resources. The algorithm serves as a tool to prompt providers to consider key decision points in the course of an episode of care.

Although this CPG represents the state of the art practice on the date of its publication, medical practice is evolving and this evolution requires continuous updating of published information. New technology and more research will improve patient care in the future. The CPG can assist in identifying priority areas for research and optimal allocation of resources. Future studies examining the results of CPG implementation may lead to the development of new evidence particularly relevant to clinical practice.

Implementation Tools

Chart Documentation/Checklists/Forms

Clinical Algorithm

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

Resources

Slide Presentation

Wall Poster

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Management of Type 2 Diabetes Mellitus in Primary Care Work Group. VA/DoD clinical practice guideline for the management of type 2 diabetes mellitus in primary care. Version 5.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Apr. 160 p. [178 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Apr

Guideline Developer(s)

Department of Defense - Federal Government Agency [U.S.]

Department of Veterans Affairs - Federal Government Agency [U.S.]

Veterans Health Administration - Federal Government Agency [U.S.]

Source(s) of Funding

United States Government

Guideline Committee

The Management of Type 2 Diabetes Mellitus in Primary Care Work Group

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Financial Disclosures/Conflicts of Interest

At the start of this guideline development process and at other key points throughout, the project team was required to submit disclosure statements to reveal any areas of potential conflict of interest (COI) in the past 24 months. Verbal affirmations of no COI were used as necessary during meetings throughout the guideline development process. The project team was also subject to random web-based surveillance (e.g., ProPublica).

If a project team member reported a COI (actual or potential), measures were in place to mitigate the introduction of bias into the guideline development process. Identified COIs would be reported to the Office of Evidence Based Practice and disclosed to the Evidence-Based Practice Work Group (EBPWG) in tandem with their review of the evidence and development of recommendations. The EBPWG and the diabetes mellitus clinical practice guideline (DM CPG) Work Group would then determine whether or not action, such as restricting participation and/or voting on sections related to the conflict or removal from the Work Group, was necessary. If deemed necessary, action to mitigate the COI was taken by the Champions and Office of Evidence Based Practice, based on the level and extent of involvement.

In order to mitigate the risk of bias while maximizing the contributions of those with expertise in a specific area of DM, the Champions asked Work Group members to disclose relevant relationships during related guideline development discussions. Members with potential COIs contributed to the discussions related to their particular areas of expertise as well as the overarching guideline document in order to ensure differing viewpoints and experiences were adequately represented.

The initially appointed Department of Defense (DoD) Champion disclosed a COI at the in-person meeting and Department of Veterans Affairs (VA) and DoD Leadership determined the COI would preclude him from continuing his role on the DM CPG Work Group. A DM CPG Work Group member, was selected as the new DoD Champion. The work on the guideline when the initial DoD Champion was present was reviewed and steps were taken to ensure that no biases were introduced and that the initial work on the DM CPG with the former DoD Champion did not negatively affect the objectivity of the DM CPG development.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Department of Veteran Affairs, Department of Defense. VA/DoD clinical practice guideline for the management of diabetes mellitus. Washington (DC): Department of Veteran Affairs, Department of Defense; 2010 Aug. 146 p.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Department of Veterans Affairs (VA) Web site.

Availability of Companion Documents

The following is available:

- VA/DOD clinical practice guideline for the management of type 2 diabetes mellitus in primary care. Clinician summary. Washington (DC): Department of Veterans Affairs (U.S.); 2017. 34 p. Available in from the Department of Veterans Affairs (VA) Web site.
- VA/DOD clinical practice guideline for the management of type 2 diabetes mellitus in primary care. Pocket card. Washington (DC): Department of Veterans Affairs (U.S.); 2017. 13 p. Available in from the VA Web site.
- Guideline for guidelines. Washington (DC): Department of Veterans Affairs; 2013 Apr 10. 26 p. Available from the VA Web site.
- Putting clinical practice guidelines to work in VHA. Washington (DC): Department of Veterans Affairs. 64 p. Available from the VA Web site.

In addition, a number of other patient-provider tools, including checklists, charts, posters, and a slide presentation, are available on the VA Web site.

Patient Resources

The following is available:

- VA/DoD clinical practice guideline for the management of type 2 diabetes mellitus in primary care. Patient guide. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Apr. 6 p. Available from the Department of Veterans Affairs (VA) Web site.

In addition, a number of other patient-provider tools, including patient logs, a booklet, and a brochure, are available on the VA Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI on February 9, 2001. The information was verified by the guideline developer on November 2, 2001. This summary was updated by ECRI on August 13, 2004. The information was verified by the guideline developer on November 15, 2004. This summary was updated by ECRI on January 11, 2006 following the U.S. Food and Drug Administration advisory on rosiglitazone. This summary was updated by ECRI Institute on September 5, 2007 following the U.S. Food and Drug Administration advisory on the Thiazolidinedione class of antidiabetic drugs. This summary was updated by ECRI Institute on November 28, 2007 following the U.S. Food and Drug Administration advisory on the Avandia (rosiglitazone maleate) Tablets. This summary was updated by ECRI Institute on March 10, 2008 following the U.S. Food and Drug Administration advisory on Avandia (rosiglitazone maleate). This summary was updated by ECRI Institute on March 4, 2011. This summary was updated by ECRI Institute on June 27, 2011 following the U.S. Food and Drug Administration advisory on Zocor (simvastatin). This summary was updated by ECRI Institute on April 13, 2012 following the U.S. Food and Drug Administration advisories on Statin Drugs and Statins and HIV or Hepatitis C drugs. This summary was updated by ECRI Institute on April 4, 2014 following the U.S. Food and Drug Administration (FDA) advisory on Rosiglitazone-containing Diabetes Medicines. This summary was updated by ECRI Institute on September 15, 2015 following the U.S. Food and Drug Administration (FDA) advisory on DPP-4 Inhibitors for Type 2 Diabetes. This summary was updated by ECRI Institute on June 8, 2017. The updated information was verified by the guideline developer on July 6, 2017.

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